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FDA Approves Baxter's GAMMAGARD Liquid 10% for Patients with Primary Immunodeficiency Disorders

Formulation, purification and packaging advancements provide benefits to healthcare professionals and patients

DEERFIELD, Ill., May 2, 2005 – Baxter Healthcare Corporation announced today that the U. S. Food and Drug Administration (FDA) has approved GAMMAGARD ® Liquid [Immune Globulin Intravenous (Human)] (IGIV) 10% Solution for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. Primary immunodeficiency is a group of genetic disorders in which the immune system fails to produce adequate amounts of antibodies, thereby predisposing individuals to increased risk of infection. The company plans to launch the plasma-based therapy in the fourth quarter of this year.

GAMMAGARD Liquid 10% offers improved convenience for healthcare professionals and patients. The ready-to-use, sterile preparation of GAMMAGARD Liquid 10% eliminates the need for reconstitution. In addition, its high concentration, compared to 5% concentrations, allows for a reduction in the length of infusion, reducing the infusion volume and saving time for both patients and healthcare professionals.

The safety of GAMMAGARD Liquid 10% has been demonstrated in a wide spectrum of patients with primary immunodeficiency disorders. Baxter produces the therapy using a three-step viral reduction process, a unique combination used to help ensure viral safety. GAMMAGARD Liquid 10% is free of added sugar, sodium, and preservatives. In addition, the packaging is latex-free.

“The approval of GAMMAGARD Liquid 10% is an exciting milestone in the treatment of primary immunodeficiency disorders, allowing for increased convenience to help patients best manage their health,” said Fred Modell, president and co-founder, Jeffrey Modell Foundation.

“As researchers continue to increase their knowledge and understanding of primary immunodeficiency disorders, the approval of this next generation IGIV will truly benefit patients with these disorders,” said Marcia Boyle, chairman and chief executive officer, Immune Deficiency Foundation. “The Immune Deficiency Foundation applauds Baxter for its commitment to providing therapies for our community.”

The approval was based on a Phase III, multicenter study of 61 patients between the ages of 6 and 72 years who were treated with 300 to 600 mg/kg every 21 to 28 days for 12 months. In this study, no validated acute serious bacterial infections occurred in any of the treated subjects.

“During the clinical trial, we found that GAMMAGARD Liquid 10% was safe and effective in the treatment of patients with primary immunodeficiency disorders,” said Joseph Church, M.D., Professor of Clinical Pediatrics, Keck School of Medicine at the University of Southern California, Head of the Division of Clinical Immunology and Allergy at Childrens Hospital Los Angeles and a lead investigator in the clinical trial. “In addition, the production of GAMMAGARD Liquid 10% incorporates a three-step viral reduction process that may improve viral safety.”

Baxter intends to launch GAMMAGARD Liquid 10% in five vial sizes (1g, 2.5g, 5g, 10g and 20g). The various vial sizes will allow for tailored dosing and help reduce waste.

Healthcare institutions will also benefit from the therapy's recommended storage conditions. GAMMAGARD Liquid 10% can be stored for up to nine months at room temperature, or for up to 36 months if kept under refrigeration.

“We developed this next generation IGIV therapy in direct response to the needs of patients and healthcare professionals,” said Joy Amundson, president of Baxter's BioScience business. “We are proud to add this important innovation to Baxter's 50-year history and commitment to safe and effective plasma therapies.”

About GAMMAGARD Liquid 10%

GAMMAGARD Liquid 10% is a ready-to-use, sterile preparation of highly purified and concentrated immunoglobulin G (IgG) antibodies. GAMMAGARD Liquid 10% is processed from human plasma and contains a broad spectrum of IgG antibodies against bacterial and viral agents. The quality of GAMMAGARD Liquid 10% begins with the donor selection process and continues throughout plasma collection, which only occurs at FDA-approved blood establishments, and plasma preparation. To further support the margin of safety, three validated, independent and effective virus inactivation/removal steps have been integrated into processing and formulation, namely solvent/detergent (S/D) treatment, 35 nanometer filtration, and a low pH incubation at elevated temperature.

Baxter will continue to supply its current GAMMAGARD S/D to those patients who require a low Immunoglobulin A (IgA) therapy.

About Primary Immunodeficiency Disorders

Primary immunodeficiency disorders encompass more than 100 diseases caused by an immune system that does not function correctly. According to the Immune Deficiency Foundation, approximately 50,000 persons in the United States have one of the primary immunodeficiency disorders. For many people with primary immunodeficiency, the cause is a lack of antibodies. IGIV therapy can help restore IgG levels to near normal, helping the immune system function properly and prevent infections or fight them when they occur.

Important Safety Information

GAMMAGARD Liquid 10% is contraindicated in patients with known anaphylactic or severe hypersensitivity responses to Immune Globulin (Human). Patients with severe selective IgA deficiency (IgA < 0.05 g/L) may develop anti-IgA antibodies that can result in a severe anaphylactic reaction. Such patients should only receive intravenous immune globulin with utmost caution and in a setting where supportive care is available for treating life-threatening reactions.

Black Box Warning : IGIV products have been associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. While these reports of renal dysfunction and acute renal failure have been associated with the use of many of the licensed IGIV products, those containing sucrose as a stabilizer accounted for a disproportionate share of the total number. GAMMAGARD Liquid 10% does not contain sucrose.

GAMMAGARD Liquid 10% is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, such as viruses, that can cause disease.

The potential risks and benefits of IGIV should be weighed against those of alternative therapies for all patients for whom IGIV administration is being considered.

Please visit www.baxter.com for full prescribing information.

About Baxter

Baxter Healthcare Corporation is the principal U.S. operating subsidiary of Baxter International Inc. (NYSE: BAX). Baxter International Inc., through its subsidiaries, assists

healthcare professionals and their patients with treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. For more information about Baxter, please visit www.baxter.com .

Statements in this press release including but not limited to Baxter's intention to launch GAMMAGARD Liquid 10% in the fourth quarter of this year are forward-looking statements that involve risks and uncertainties. Actual results could differ materially from the above forward-looking statements as a result of certain factors, including the risk and uncertainty related to actions of regulatory bodies and other government authorities, including the FDA and foreign counterparts that could delay, limit or suspend product sales and distribution; product quality and/or patient safety concerns leading to product recalls, withdrawals, launch delays or declining sales; product development risks; technological advances in the medical field; demand for and market acceptance risks for new and existing products and other technologies; reimbursement policies of government agencies and private payers; internal and external factors that could impact commercialization; and other risks detailed in the company's filings with the Securities and Exchange Commission. The company disclaims any current intention to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise, and all forward-looking statements speak only as of the time when made. Actual results or experience could differ materially from the forward-looking statements.

For Additional Information

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GAMMAGARD Liquid Package Insert **(pdf 144k)**

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